

AMENDMENTS TO THE SPECIFICATION:

Please amend the paragraph at page 2, lines 3 to 12, as follows:

The invention provides a process for making levetiracetam, levetiracetam produced by the process of the invention and pharmaceutical compositions containing levetiracetam. The process entails reacting (S)-2-amino-butanamide hydrochloride and ~~4-chlorobutryl~~ 4-chlorobutyryl chloride in acetonitrile or methyl ~~tert-butyl~~ tert-butyl ether, in the presence of a strong base, and recovering the crude levetiracetam. Unlike the prior art, the process does not require a catalyst, such as tetrabutylammonium bromide. The process is a one step condensation reaction in which acetonitrile or methyl ~~tert-butyl~~ tert-butyl ether is used as the reaction solvent. The process may enable the production of levetiracetam of high chemical purity, *i.e.*, having less than 0.2 % impurities in the crude product and less than 0.1% impurities in the crystallized product.

Please amend the paragraphs at page 2, lines 19 to 30, as follows:

In one aspect, the invention provides a process for preparing (S)- α -ethyl-2-oxo-1-pyrrolidineacetamide (levetiracetam) comprising reacting (S)-2-amino-butanamide hydrochloride and ~~4-chlorobutryl~~ 4-chlorobutyryl chloride in acetonitrile, in the presence of a strong base, and recovering the crude levetiracetam.

In another aspect, the invention provides a process for preparing (S)- α -ethyl-2-oxo-1-pyrrolidineacetamide (levetiracetam) comprising reacting (S)-2-amino-butanamide hydrochloride and ~~4-chlorobutryl~~ 4-chlorobutyryl chloride in methyl ~~tert-butyl~~ tert-butyl ether, in the presence of a strong base, and recovering the crude levetiracetam.

In a third aspect, the invention provides a process for preparing (S)- α -ethyl-2-oxo-1-pyrrolidineacetamide which comprises cyclizing (S)-N-[1-(aminocarbonyl)propyl]-4-chlorobutanamide, in a solvent selected from the group consisting of acetonitrile and ~~methyltertbutyl~~ methyl tert-butyl ether, in the presence of a strong base.

Please amend the paragraph at page 3, lines 3 to 8, as follows:

In a fifth aspect, the invention provides a process for preparing (S)- α -ethyl-2-oxo-1-pyrrolidineacetamide (levetiracetam) comprising reacting (S)-2-amino-butanamide hydrochloride and ~~4-chlorobutryl~~ 4-chlorobutyryl chloride, in an inert solvent, in the absence of a catalyst, and recovering the crude levetiracetam. The reaction preferably takes place in

the presence of a strong base. The inert solvent is preferably acetonitrile or ~~methyl tert-butyl~~ methyl tert-butyl ether.

Please amend the paragraph at page 3, lines 20 to 24, as follows:

The reaction temperature for the processes is preferably maintained at between about -15 degrees ~~eeleius~~ Celsius and about + 25 degrees ~~eeleius~~ Celsius, more preferably between about -15 degrees ~~eeleius~~ Celsius and about + 15 degrees ~~eeleius~~ Celsius, even more preferably between about -15 degrees ~~eeleius~~ Celsius and + 10 degrees ~~eeleius~~ Celsius, and most preferably between about 0 degrees ~~eeleius~~ Celsius and + 5 degrees ~~eeleius~~ Celsius.

Please amend the paragraph at page 3, line 32, to page 4, line 7, as follows:

The crude levetiracetam may be purified by crystallization or recrystallization from an organic solvent or a mixture of organic solvents. The organic solvent is preferably an alcohol, a ketone, a hydrocarbon, an ether, an ester or mixtures thereof. Examples of alcohols that may be used include isopropyl alcohol, ethanol, methanol, butanol or mixtures thereof. Examples of ketones that may be used include methyl ethyl ketone, methyl isobutyl ketone, or mixtures thereof. Examples of hydrocarbons that may be used include toluene, hexane, or mixtures thereof. Examples of ethers that may be used include methyl ~~tert-butyl~~ tert-butyl ether. Examples of esters that may be used include isobutyl acetate, ethyl acetate or mixtures thereof.

Please amend the paragraph at page 4, line 32, to page 5, line 2, as follows:

Pharmaceutical ~~formulations~~ formulations of the present invention contain levetiracetam and one or more excipients or adjuvants. Selection of excipients and the amounts to use may be readily determined by the formulation scientist based upon experience and consideration of standard procedures and reference works in the field.

Please amend the paragraph at page 13, lines 8 to 20, as follows:

27.7 g (0.2 M) ABA HCl is added to 80 g (0.56 M) powdered K₂CO₃ in 500 ml ACN and the mixture is stirred at room temperature for 30 minutes and then cooled to about 0 degrees ~~Celeius~~ Celsius. A solution of 4-chlorobutyryl chloride, 31 g (0.22 M) in 100 ml of ACN is added to the mixture over a period of about 1 hour while the temperature is kept at between about 0-3 degrees ~~Celeius~~ Celsius. The reaction mixture is brought to room temperature and stirred for 2 hours. The temperature of the reaction mixture is raised to 30

degrees Celsius and 8.4 g (0.21 M) sodium hydroxide is added. After 90 minutes, another charge of 8.4 g sodium hydroxide is introduced and the mixture is stirred at 30 degrees Celsius for another 150 minutes. The suspension is filtered and the solid is washed with 0.25 liters of ACN. The filtrate and washes are combined and evaporated in vacuo to a solid which is crystallized from about 80 ml of hot ACN leading to a crude 26 g Levetiracetam (77 % purity). Recrystallization of the crude levetiracetam from 170 ml hot ethylacetate gives 23.5 g of the final product.